(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 324 279 A1**

(12) EUROPEAN PATENT APPLICATION

(21) Application number: 88312388.7

(51) Int. Cl.4: **A61B 5/10 , A61B 17/56**

(22) Date of filing: 29.12.88

(30) Priority: 29.12.87 GB 8730257

(43) Date of publication of application:
19.07.89 Bulletin 89/29

(84) Designated Contracting States:
AT BE CH DE ES FR GB GR IT LI LU NL SE

(71) Applicant: **Richardson, James Bruce, Dr.**
3 Whitmore Road
Newcastle-under-Lyme ST5 3LY(GB)

Applicant: **Shah, Khalid Mahmud**
Western Infirmary Dumbarton Road
Glasgow G11 6NT(GB)

Applicant: **Roberts, Andrew**
1 Black Lane
Pilsley Derbyshire S45 8HJ(GB)

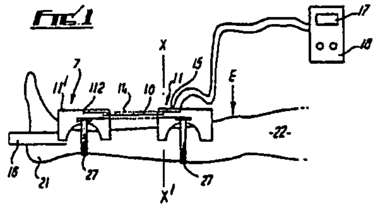
(72) Inventor: **Richardson, James Bruce, Dr.**
3 Whitmore Road
Newcastle-under-Lyme ST5 3LY(GB)
Inventor: **Shah, Khalid Mahmud**
Western Infirmary Dumbarton Road
Glasgow G11 6NT(GB)
Inventor: **Roberts, Andrew**
1 Black Lane
Pilsley Derbyshire S45 8HJ(GB)

(74) Representative: **Pacitti, Pierpaolo A.M.E. et al**
Murgitroyd and Company Mitchell House 333
Bath Street
Glasgow G2 4ER Scotland(GB)

(54) System for measuring fracture stiffness.

(57) This invention relates to a system for measuring fracture stiffness, which is indicative of fracture healing. It is of particular application to fractures of the bones of limbs. The apparatus comprising a goniometer (10) which is positionable to run substantially parallel to the long axis of the bone having the fracture and which has one end connected with a first spacer (11), placed axially to one side of the fracture (8), and the other end connected with a second spacer (11'), placed axially to another side of the fracture, and said apparatus including means (15, 16) to measure the signal of the goniometer to obtain a measurement of angular deformation on the application of a load, said measurement being representative of fracture stiffness.

FIG 1



EP 0 324 279 A1

System for Measuring Fracture Stiffness

This invention relates to a system for measuring fracture stiffness, which is indicative of fracture healing. The invention is particularly appliable to fractures of the bones of limbs.

The chief function of the skeleton is to support, ie structual, and this function is lost when a bone fails by fracture. Fracture healing returns this function, and therefore a mechanical measure may be appropriately employed to measure healing. The gradual change in tissue during healing can be characterised by its stiffness, changing from a Young's modulus of elasticity expressed as 0.005 Kp/mm2 for granulation tissue, as found in the new bone of a bridging callus, to 2000 Kp/mm2 for mature bone, representing a 400,000-fold change.

A fracture stiffness measurement as a functional measure of healing helps in two areas: comparisions between patients, and monitoring progress of an individual patient. The principle demands on the measuring system will be for accuracy of the stiffness measurement, to form a measure as a known, trusted and accurate standard or series of standards in the matter of comparison, and for precision of the stiffness measurement, to assess an individual patient's progress wherein the changes, especially on a day to day basis, may be very slight.

It is known that a fracture stiffness measurement is a good indicator for fracture healing and it is known that the degree of angular deflection of the healing tissue bridging the fracture is a good measurement of the stiffness, but conventional and previous methods and apparatus have been unsuccessful at producing an accurate, precise system of measurement, particularly when the fracture is not subjected to invasive apparatus such as bone screws, and which system is also relatively painless and safe.

Prior systems include the use of temporary percutanous bone screws inserted under anaesthesia, the movement of which under the application of a load is a measurement of fracture stiffness. This system is somewhat extreme and has the disadvantage of allowing little in the way of an assessment of the progress of healing, as patients do not tolerate frequently repeated measurements.

A radiographic prior art method has high errors for the precise measurements required for individual patient progress and it can not be improved by the simple procedure of repeating the tests as this would involve excessive exposure to X-rays.

An inaccurate but simple method of measuring fracture stiffness is to use a dial gauge micrometer to determine the amount of bending during application of a fixed torque to patients with external fixation. As expected the deflection fell with increasing stiffness and, by calculation these measurements have been expressed as a stiffness to allow comparison for other workers. However, the difficulties of obtaining a precise and accurate reading from such micrometers are known and the system is also not applicable to non-invasive apparatus.

Other system have used strain gauges bonded to a patient's fixator. Calculation of the fixator's stiffness is required to estimate the fracture stiffness. However these systems do have the advantage of repeatability and precision for an individual's progress.

As abovementioned, there is a need for an objective stiffness measurement of reasonable accuracy to allow safer decisions as to when to remove fixators, external or invasive, and allow independent weight bearing. The commonest major complication, noted after use of certain prior art systems, is refracture after removal of the fixator or a significant loss of alignment, particularly in those limbs allowed free of support at a lower level of stiffness. Yet the fixators must not be in place too long, as this leads to further complications, such as stiffness of the joints.

It is highly desirable, and not unreasonable to anticipate, the use in future of one standard measurement to calculate the safe levels to allow independent weight-bearing; if a patient were heavy, or a fracture angulated, then higher levels of stiffness might be appropriate, but for purposes of a comparative trial, or to allow, for instance, international comparisons, one level of healing stiffness is appropriate.

Clearly also, another requirement of any fracture stiffness measurment apparatus is one that does not directly measure the strength of the bone (by weighting for example) as to do so would result in re-fracturing.

It is an object of the present invention to obviate or mitigate the abovementioned disadvantages.

According to th present invention there is provided apparatus for measuring fracture stiffness, said apparatus comprising a goniometer which is postionable to run substantially parallel to the long axis of the bone having the fracture and which has one end connected with a first spacer, placed axially to one side of the fracture, and the other end connected with a second spacer, placed axially to another side of the fracture, and said apparatus including means to measure the signal of the goniometer to obtain a measurement of angular deformation on the application of a load, said measurement being representativ of

fracture stiffness.

Preferably, the apparatus includes means to measure a load applied to one side of the fracture and calculating means to calculate angular deformation with reference to the load applied, which calculating means may be in the form of a computer.

Preferably, the goniometer is an electrogoniometer.

Preferably, there is a load cell placed distally of the fracture and the load is applied proximally. The goniometer runs parallel to the anterior aspect of the bone and the load is applied at right angles to the long axis and on the anterior of the bone. As the bone is unsupported along much of its length, such that the pull of gravity and limb weight aids the load application, therefore the bones bends downwards at the fracture point.

The spacers in the case of invasive fixators are in the form of arcuate clamp plates clampable to the invasive fixators, such as bone screws or bone pins, and of a form to position the goniometer substantially parallel to the anterior long axis of the bone, irrespective of the position of the fixators. These spacers bring the goniometer into the same vertical plane as the fracture and thus prevent errors due to rotation at the fracture.

The spacers in the case of non-invasive fixators, are in the form of bridges moulded to fit the limb having the fractured bone.

The bridges depend on good contact with the skin that overlies the generally anterior aspect of limb and employ a system of strapping having a three-point fixation including an elastic strap. A clamping system is used for fractures near the ankle. This clamp applies compression to the malleoli and thus achieves good stability.

The bridges may be connected to a cast or stocking or brace to reduce the skin movement effect on the measurement.

The means to measure the signal of the goniometer is connected with one spacer and includes an amplifier; said means may also be interconnected with said load measuring means and said calculating means.

Preferably, there are included means for to compare the measurement with a reference measurement, either a reference measurement of the same fracture at an earlier date or measurement of the stiffness of the intact limb.

Preferably, there are means to record the reference measurement, particularly the reference measurement from apparatus applied to an invasive fixator system, and means to objectively compare such a measurement with a measurement obtained from apparatus applied to non-invasive or invasive fixator systems.

Embodiments of the present invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Fig. 1 is a side elevation of one embodiment of apparatus for measuring fracture stiffness according to the present invention, in use on a tibial fracture;

Fig. 2 is a sectional view on x-x′ of Fig. 1;

Fig. 3 is a schematic illustration of the angular deflection measured by the system of Figs 1 and 2;

Fig. 4 is a perspective view from one side of the goniometer of Figs 1 and 2;

Fig. 5 is a cross-sectional view of the goniometer of

Fig. 4;

Fig. 6 is a schematic illustration of a second embodiment of apparatus according to the present invention, in use on a tibial fracture; and,

Fig. 7 is a schematic illustration of an embodiment of a clamp of apparatus according to the present invention, in use on an tibial fracture near the ankle.

Referring to Figs 1 to 7, there is shown apparatus 7 of the present invention for measuring fracture stiffness, fracture stiffness being indicative of the healing of a fracture 8 and being calculated by measuring the angular deflection of the bone 9 on the fracture site 7.

The apparatus 7 comprises a goniometer 10 which is positionable to run vertically above the anterior long axis of the bone 9 having the fracture 8. It is positionable by means of spacers 11, with one end of the goniometer 10 attached to a first spacer 11 placed axially to one side of the fracture 8 and the other end attached to a second spacer 11′ placed axially to the other side of the fracture 8.

A goniomet r 10 is an instrument to measure angles. A goniometer is an instrument to measure angles. Previous prior art designs have limitations of sensitivity or are inaccurate du to changes in their length during flexion which alters their surface strain. A high gain goniometer has been designed on a polycarbonat or other suitable beam. Strain gauges are bonded to its full length on both surfaces to maintain

accuracy by covering the area within which the point of rotation of the limb will probably lie. The spacers include a sliding element so that altering the length of the device does not of itself produce angulation.

The electrogoniometer 10 used in the present invention, although previously known, has only been used before in the assessment of joint function in patients and thus used generally at a range of over 90° flexion. Yet it is infinitely sensitive, is relatively stable to temperature changes and has very littl resistance to movement. It is therefore most appropriate as a means to measure the very slight angular deflection of a fracture site on the application of a load, but until now it had not been realised for this application; for fracture stiffness measurements angulation is of 2° or less and, importantly, over such slight angulation the force applied to the transducer does not change significantly.

More specifically, the goniometer 10 used here comprises a thin skim 12 of steel with wires 13,13′, one along either side (see Figs 4 and 5) of the skim 12 and wires 13,13′ being wrapped in a protective coiled spring 14. The wires 13,13′ act as a strain gauges, their output having a linear relationship with the subtended angle. If the load applied is known, the amount of bending can be measured, this angular deflection being representative of fracture stiffness and, hence, fracture healing.

The apparatus 7 therefore includes means 15 to measure the signal from the goniometer 10, these means being connected to one spacer 11.

The apparatus 7 also includes means 16 to measure the load applied and means 17 to calculate the angular deflection with reference to this load-applied measurement. The goniometer signal measuring means 15 includes an amplifier 18 which connects with the calculating means 17, which is in the form of a computer with print-out 19 and screen display 20.

The load measuring means 16 are in the form of bathroom scales, which in the case of a tibial fracture are placed distally under the heel 21 or attached to the heel-based spacer 11′ of a patient and the load is applied proximally to the fracture at E. The load is applied at right angles to the long axis of the bone 9 which is placed unsupported along which of its length such that the load may be applied to the anterior and downwardly, aided by the pull of gravity and limb's 22 weight.

On the application of a load, the fractured tibia 9 bends downwardly; the distance over which the goniometer 10 extends is thus decreased and the goniometer bows. The degrees of angular deflection (upsilon) is calculated by knowing the distance (y) from the point load measured (F) to the fracture site 8 (see Fig. 6).

Applied Torque	=	F y
Fracture Stiffness	=	F y

The errors between measurement have a 95% confidence limit of +/-12%.

Comparison with AP X-ray results shows that the goniometer 10 provides accurate results.

In the embodiment of Figs 5 and 6, the fixators are invasive being in the form of bone screws 23. The spacers 11 are therefore in the form of arcuate clamps 111, clampable to the screws 23, by a screw-threaded tightening nut 24 and back plate 25 and being of a form to position the goniometer 10 substantially parallel to the antieror long axis of the bone 9.

The spacers 11 of the embodiment of Figs 1 and 2 are for use with a non-invasive fixator system. The spacers 11 are in the form of orthoplast bridges 112. As the soft tissue attachment of the goniometer is a potential source of error in the system 7, each bridge 112 is developed with good contact with the skin that overlies the anterior aspect of the tibia 9, and a system of strapping 2 that uses a 3-point fixation, including an elastic strap 27.

In the embodiment of Fig 7, a clamping system 210 is used. This system is particularly useful for fractures near the ankle wherein the normal bridge would have insufficient tibia to attach to. The clamp 211 applies compression to the malleoli and this achieves good stability.

This invention allows an objective measure to be formulated to allow comparison of patients treated conservatively against those with external fixation; indeed, the former serves as the standard by which the latter are tested.

The apparatus 7 is also beneficial in that it is non-invasive, painless and not stressful for the patients, as it requires only a few degrees of angulation.

With such apparatus the precise measurement of an individual bone may be taken and this allows monitoring of the progress of healing for a specific patient. Even small changes in stiffness can be considered significant and can be studied with a view to the management of aspects of treatm nt, such as the rate of return to full w ight-bearing. The clincian needs such information, as removal of splintage or fixators at too early a stage can lead to refracture or loss of alignment yet if allow d to remain for too long

the liklihood increases of having further complications such as increased stiffness.

Once an objective standard is achieved one pati nt may be compared to another and this need not be limited to one type of treatment, so allowing comparison of different types of treatment.

An objective measurement will indicate complications; for example if low levels of stiffness persist, compared to a normal progress of individuals with a similar injury, operative intervention may be indicated. Indeed, an objectively defined healing time can be compared to clinical parameters of healing, and used to analyse the many variables that affect the progress of fracture healing in patients.

An objective standard will help predict the time to healing the certainty of prediction increasing as the stiffness rises. Such prediction will be useful on the individual basis as well as for comparison.

The use of fracture stiffness measurement also allows an objective testing of the effect of passive cyclic micromovement applied in the early weeks following injury.

The progress of fracture healing when there is only external fixators has previously been particularly difficult to assess. The objective stiffness measurement allows a safer decision of when to remove the tixation and allow independent weight bearing.

There is a particular need to compare the use of functional fixators with functional bracing for tibial fractures, particularly as the proposed indications for each method of management increase and overlap considerably in tibial fracture management. The present stiffness measuring system as an objective and sensitive measuring system and being applicable to invasive and non-invasive fixators, provides some of the answers regarding which method of treatment is appropriate in cases of tibial or other fractures.

The overall accuracy of the apparatus is improved by taking the mean of several repeated tests, and rapid feedback from a test to aid in the indentification of errors. The means for carrying out such comparisons means includes software for a portable computer that allows a visual display of output and calculates the fracture stiffness and predicts the time at which the individual fracture will heal. The software communicates with a database that holds data on a series of patients to allow comparison and assessment of progress.

Further accuracy may be obtained by the use of digitised load transducer in addition to a digitised output to the goniometer.

Modifications and improvements may be incorporated without departing from the scope of the invention.

Claims

1. Apparatus for measuring fracture stiffness, said apparatus comprising a gonimeter which is positionable to run substantially parallel to the long axis of the bone having the fracture and which has one end connected with a first spacer, placed axially to one side of the fracture, and the other end connected with a second spacer, placed axially to another side of the fracture, and said apparatus including means to measure the signal of the goniometer to obtain a measurement of angular deformation on the application of a load, said measurement being representative of fracture stiffness.

2. Apparatus according to Claim 1, wherein there are means to measure a load applied to one side of the fracture and calculating means to calculate angular deformation with reference to the load applied.

3. Apparatus according to either Claim 1 or 2, wherein the goniometer is an electrogoniometer.

4. Apparatus according to any one of the preceding Claims, wherein a load cell is placed distally of the fracture and the load is applied proximally.

5. Apparatus according to any one of the preceding Claims, wherein the spacers are in the form of arcuate clamp plates clampable to invasive fixators, and of a form to position the goniometer substantially parallel to the anterior long axis of the bone, irrespective of the position of the fixators, and to bring the goniometer into the same vertical plane as the fracture.

6. Apparatus according to anyone of Claims 1 to 5, wherein the spacers are in the form of bridges moulded to fit the limb having the fracture.

7. Apparatus according to Fig 6, wherein the bridges employ a system of strapping having a three-point fixation including an elastic strap.

8. Apparatus according to Claim 6 or 7, wherein for a fracture near the ankle bone the distal bridge includes clamping means.

9. Apparatus according to any one of the preceding Claims, wherein the means to measure the signal of the goniometer is connected with one spacer and includes an amplifier.

10. Apparatus according to any one of the preceding Claims, wherein there are included means for comparing the measurement with a reference measurement, either a reference measurement of the same fracture at an earlier date or a measurement of the stiffness of the intact limb.

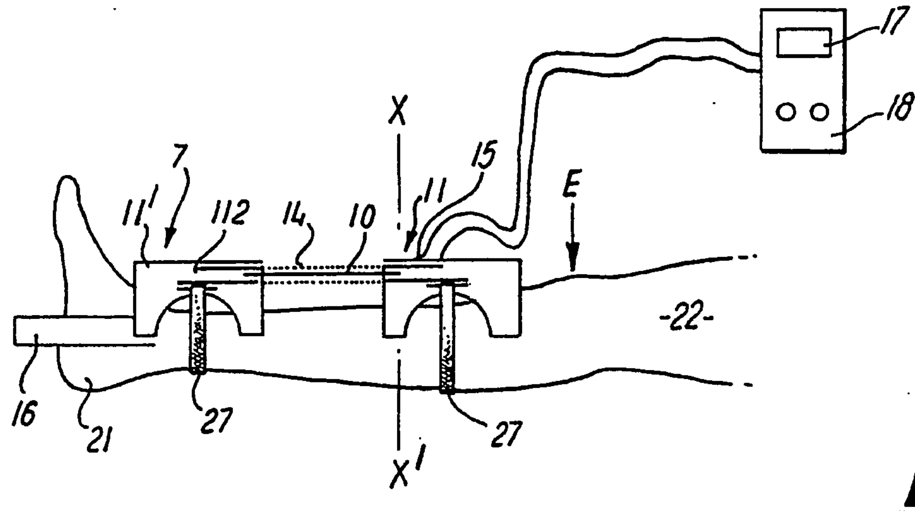


FIG. 1

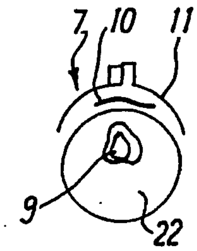


FIG. 2

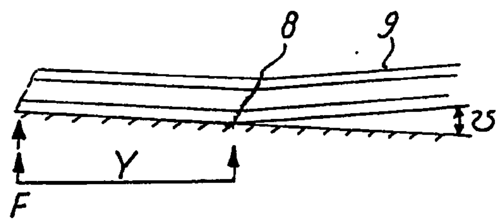


FIG. 3

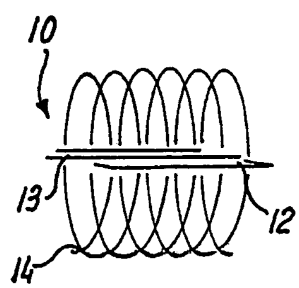


FIG. 4

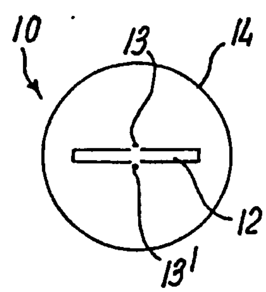


FIG. 5

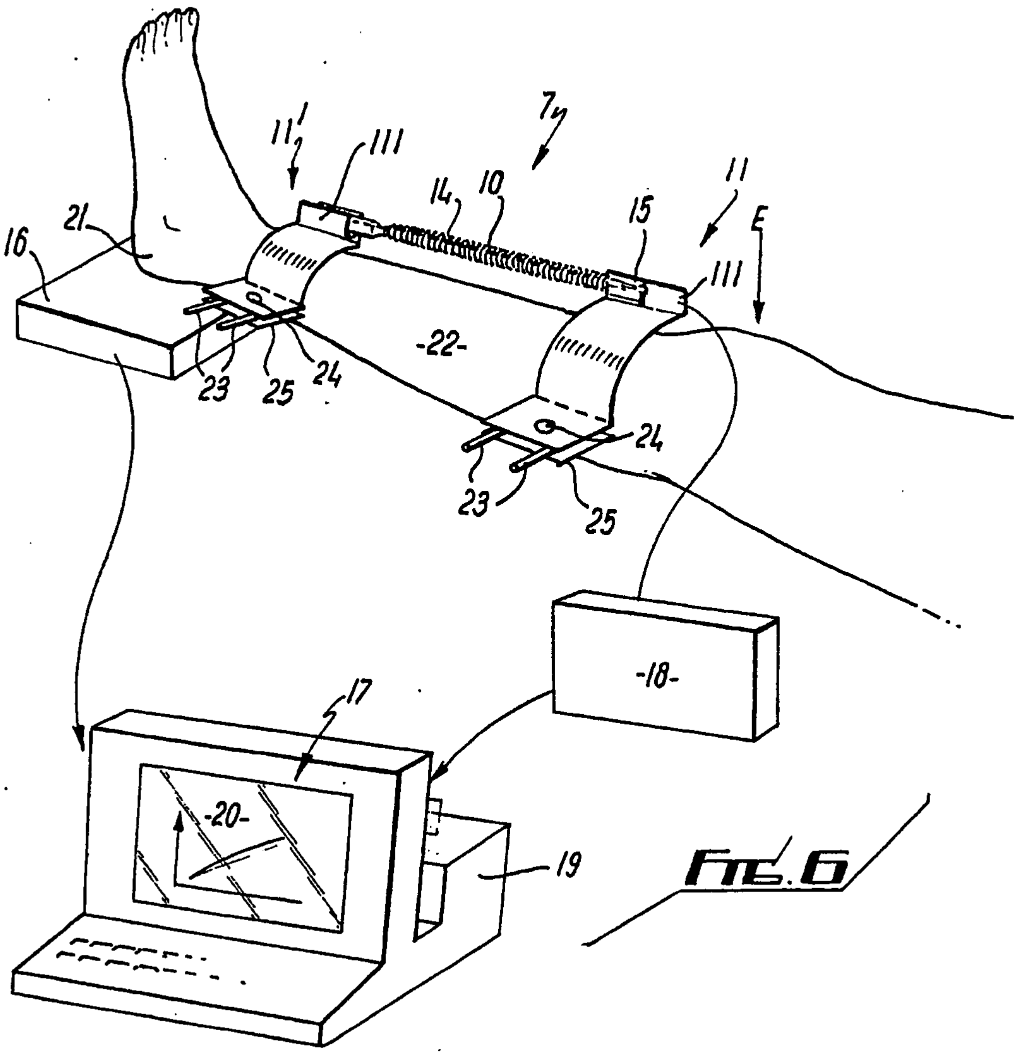

7
11'
111
14
10
11
15
E
111
16
21
-22-
23
25
24
24
23
25
-18-
17
-20-
19

FIG. 6

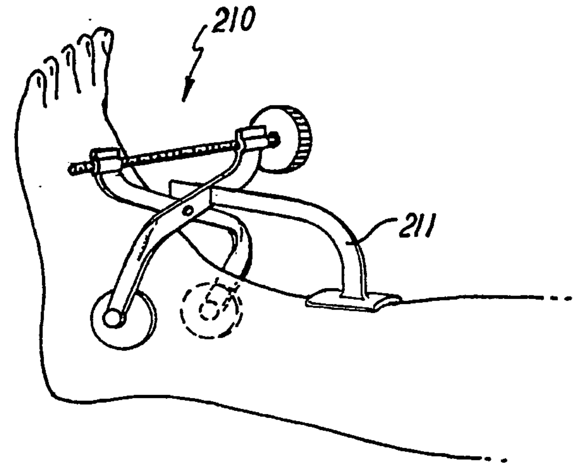

210
211

FIG. 7

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 88 31 2388

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
Y	ENGINEERING IN MEDICINE vol. 16, no. 4, October 1987, pages 229-232, London, GB; J.L. CUNNINGHAM et al.: "The measurement of stiffness of fractures treated with external fixation". * Page 229, left hand column, line 1 - page 232, right hand column, line 11; figures 1-10 *	1,2,5, 10	A 61 B 5/10 A 61 B 17/56
A	idem ---	4,6,8	
Y	ENGINEERING IN MEDICINE vol. 11, no. 3, July 1982, pages 123,124, Whitstable, GB; W.V. JAMES et al.: "A clinical electrogoniometry system". * page 123, left hand column, line 1 - page 124, left hand column, line 5; figure 1 *	1,2,5, 10	
A	idem ---	3,9	**TECHNICAL FIELDS SEARCHED (Int. Cl.4)**
A	JOURNAL A vol. 24, no. 3, July 1983, pages 139-153, Antwerpen, Belgium; R. VAN CAUTEREN: "(Unusual) sensors in (unusual) mechanical applications". * page 139, right hand column, line 14 - page 140,left hand column, line 11; figure 3 * -----	1,4	A 61 B 5/00 A 61 B 17/00

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
BERLIN	20-03-1989	WEIHS J.A.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document